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ELF ATOCHEM NORTH AMERICA, INC.

900 First Avenue, P.O. Box 1536 King of Prussia, PA 19406-0018

Tel: 215-337-6500

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August 21, 1992



#### **CERTIFIED MAIL**

#### **RETURN RECEIPT REQUESTED**

Document Processing Center (TS-790) Office of Toxic Substances U.S. Environmental Protection Agency 401 M St., S.W. Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e)

Compliance Audit Program

CAP Identification Number: 8ECAP-0026

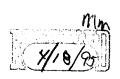
Dear Sir/Madam:

Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and Environmental Protection Agency (EPA), Atochem is submitting the enclosed final report on studies to establish skin and eye irritation potential in rabbits to the EPA. These studies do not involve effects in humans.

Nothing in this letter or the enclosed studies is considered confidential business information of Atochem.

The enclosed studies provide information on the chemicals triphenyltin chloride and triphenyltin acetate. The exact chemical name of triphenyltin chloride is chlorotriphenylstannane and its CAS number is 639-58-7. The exact chemical name of triphenyltin acetate is acetic acid, (triphenylstannyl)- and its CAS number is 63314-23-8.

The title of the enclosed report is <u>Report No. 3, Toxicity and Irritating Properties of Triphenyltin Compounds</u>. This report consists of several studies. The following is a summary of the adverse effects observed in the eye and skin irritation studies with triphenyltin chloride and triphenyltin acetate.



TSCA CAP
Triphenyltin Chloride and Triphenyltin Acetate
August 21, 1992
Page Two

Application of triphenyltin chloride and triphenyltin acetate to the intact and abraded skin of groups of six rabbits for 24 hours was corrosive to rabbit skin. Application of each test material to one eye of an additional group of rabbits was corrosive to the rabbit eye.

To our knowledge, Atochem has not previously submitted any TSCA Section 8(e) notices or premanufacture notifications on triphenyltin acetate. Atochem previously submitted a TSCA Section 8(e) notice on triphenyltin chloride. The submission was made July 31, 1992; we have not been notified by EPA of the EPA Document Control Number for this submission.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,

C.H. Farr, PhD, DABT Manager, Product Safety

and Toxicology

CHO Faw

**Enclosures** 

# THE HINE LABORATORIES

1099 FOLSOM STREET . SAN FRANCISCO 3, CALIFORNIA

Dr. C. K. Banks, Vice President Metal & Thermit Corporation Rahway, New Jersey

T-675

September 19	M 3615	
ATE ACK	SEP 24 1962	TATE ANS'D
RA	AHWAT GETERAL OFF	ICE

Dear Ken:

Attached is our Report No. 3, which deals with the toxicity and irritating properties of the triphenyltin compounds. As we had indicated to you previously and as is described in the body of the report, both the chloride and the acetate were necrotizing and destructive of corneal tissue. The compounds diluted to 1% in corn oil were only moderately irritating.

Eye irritation evaluations were also carried out on the trioctyltin oxide and the monolaurylmaleate. You will note that the monolaurylmaleate was again rated as severely irritating. This rating was assigned because of the corneal opacity and a total which averaged above 20. The trioctyltin oxide, on the other hand, was only slightly irritating.

In view of these findings I would suggest that personnel handling the severely irritating materials be furnished with suitable eye protection and that you adopt for them whatever safe-handling practices are used by your group in dealing with mineral acids. As regards the emergency first aid treatment, my suggestion is that these be directed towards immediate lavage with copious quantities of water. Our experience has been that tap water applied with sufficient pressure to give a diffuse water stream 18 inches in height automatically controlled by a constricting valve operating directly off line pressure is the most satisfactory device obtainable. These manually held sprinklers can be pointed in any direction and operated either by the person affected or by the one rendering first aid. I will send you a blueprint of the device which we have installed in a number of areas where there is a possibility of eye injury due to contact with chemical substances. We do not recommend that any especially prepared irrigation solution be dispensed throughout the plant, although follow-up treatment at the first aid room with these buffered solutions may offer some advantage. The primary task is to flood the eyes with large quantities of water, and sterility or pH at this point are not factors. If necessary, forceful immersion of the face may be employed.

I agree that your proposed treatment of dermal exposures is entirely satisfactory. We find that a detergent helps to remove many compounds somewhat more effeciently than soap itself. If the area involved is large, we generally subsequently apply a 5% boric acid lanolin ointment.

CAS: 639-58-7; 63314-23-8

Dr. C. K. Banks Page Two 9/19/62

I believe that the present report concludes the studies which we have been asked to carry out for you. When you reach a decision as to the candidate compounds for further evaluation, we will be happy to be of assistance.

I am certainly sorry to hear of Mrs. Banks' recent illness, and was sorry I could not reach you while I was in New York.

With kindest personal regards.

Cordially,

C. H. Hine, M.D., Ph. D.

Director

The Hine Laboratories, Inc.

INTRODUCTION: This study was carried out at the request of Dr. C. K. Banks, Metal & Thermit Corporation, in order to evaluate the toxicity class and irritative effect of triphenyltin chloride and triphenyltin acetate. In addition, skin and eye irritation tests were done on tri-(n-octyl)tin oxide and di-(n-octyl)tin bis-0,0'-(monolaurylmaleate).

#### Determinations included the following:

- 1. Oral range find
- 2. Vapor range find
- 3. Skin irritation (Draize)
- 4. Eye irritation undiluted products, and in the case of the triphenyltins, a 1% solution in corn oil.

#### PROCEDURE:

#### 1. Oral Range Find

Long-Evans male rats in the 200 gram range were randomized into groups of two. Each group was injected intragastrically with a single dose of triphenyltin acetate or triphenyltin chloride, after fasting. A total of seven doses of each compound were administered; these ranged from 0.08 to 5.0 gm/kg. The compounds were mixed with corn oil and tween 80 as described in our earlier reports to make a 20% suspension. Rats were observed for toxic signs and the tissues of those which died were examined grossly. All survivors were held for thirty days and weighed weekly.

#### 2. Vapor Inhalation

The powdered compounds were placed in one-inch diameter

glass vaporization tubes with glass wool to increase surface contact with the ambient air. Air flow under positive pressure was passed through the tubes and into a vented exposure chamber of 22 liter capacity where six rats were exposed for four hours. Animals were observed thereafter for thirty days.

#### 3. Skin Irritation

Each of six rabbits was shaved and lightly abraded in two areas on the skin. Approximately 0.1 gram of each compound was applied on each abraded spot and on an opposite intact area. All spots were covered with gauze and tape and the animals were encircled with Saran-wrap to prevent disturbance of the bandages. After 24 hours the coverings and compounds were removed. Readings for primary skin irritation according to the method of Draize were made at that time and again at 72 hours.

#### 4. Eye Irritation

Approximately 0.1 gram or 0.1 milliliter, depending on the compound, was placed in the conjunctival sac of one eye of each of six rabbits, the other eye serving as a control. Readings for eye irritation according to the method of Draize were made at 24, 48, and 72 hours. Additional tests were made with the two diphenyltin compounds, using 1% suspensions in corn oil.

#### RESULTS:

#### 1. Oral Range Find

Results are summarized in Tables 1 and 2. Survivors of all doses except the lowest (0.08 gm/kg) lost weight during

the first week after administration of both diphenyltin acetate and diphenyltin chloride. This weight was regained during subsequent weeks. The fractional mortality of the acetate was spread over a wider range than that of the chloride. Both may be classed as slightly to moderately toxic according to the A.I.H.A. system of classification.

It was noted, at time of posting, that rats which died as a result of doses above 1.0 gm/kg frequently had abdominal hemorrhages which appeared to originate in the caecum. Small vessels in the stomach also appeared distended or hemorrhagic.

#### 2. Vapor Inhalation

No effects whatever were seen with either triphenyltin acetate or triphenyltin chloride, either during or after exposure.

#### 3. Skin Irritation

Results are summarized in Tables 3 and 4. Both triphenyltin compounds produced eschar on abraded skin and should be considered severely irritating. Erythema and edema were produced by both compounds on intact as well as abraded skin.

Irritation was still present after 72 hours.

#### 4. Eye Irritation

Results for the triphenyltin compounds are summarized in Tables 5 - 8. Results for dioctyltin monolaurylmaleate and trioctyltin oxide are summarized in Tables 9 and 10.

Triphenyltin acetate and triphenyltin chloride both caused complete and permanent destruction of the eye and should be considered as necrotizing and destructive.

One percent suspensions of both compounds in corn oil produced moderate conjunctival irritation in most rabbits and slight corneal damage in one rabbit out of six. The corneal damage in each case appeared as a small, lightly fluorescent staining area when tested with fluorescein. These disappeared within 72 hours. The diluted triphenyltin acetate may be classed as moderately irritating and the diluted triphenyltin chloride as slightly irritating, based on the average eye irritation scores.

Dioctyltin monolaurylmaleate produced corneal damage in all six rabbits tested and should be classed as severely irritating, though not as destructive as the triphenyltin salts.

Trioctyltin oxide was irritating to the conjunctiva only and may be classed as only slightly irritating.

None of the materials tested appeared to cause pain or burning when first applied to the eye, and this suggests that damage occurs slowly rather than immediately. The damage produced by the octyltins and the 1% triphenyltin is apparently reversible, while the undiluted triphenyltins result in permanent destruction.

Table 1: Triphenyltin Acetate: Results of Intragastric Administration to Rats

Dose (gm/kg)	Mortality	Time of Death
0.08	0/2	
0.16	0/2	
0.32	1/2	9th day
0.64	1/2	8th day
1.25	1/2	8th day
2.5	2/2	7th day
5.0	2/2	1st, 4th day

LD<sub>50</sub>: Between 0.32 and 1.25 gm/kg

Table 2: Triphenyltin Chloride: Results of Intragastric Administration to Rats

Dose (gm/kg)	Mortality	Time of Death
0.08	0/2	
0.16	0/2	
0.32	0/2	
0.64	2/2	3rd, 7th day
1.25	2/2	3rd, 7th day
2.5	2/2	3rd day
5.0	2/2	2nd, 3rd day

 $LD_{50}$ : Between 0.32 and 0.64 gm/kg

Table 3: Triphenyltin Acetate: Results of Skin Irritation Tests in Rabbits

Time	Rabbit	Sec		Combined Average
		Intact	Abraded	
24 hours	1	3	3	
liours	2	2	3	
	3	3	3	
:	4	2	2	
	5	3	3	
	6	1	1	
	Average	2.3	2.5	
72 hours	1	2	4 eschar	
Hours	2	1	4 "	: :
	3	2	4 "	
	4	1	4 "	
	5	2	2	
	6	0	2	
	Average	1.3	3.3	
				2. <i>3</i> 5

Severely irritating

Table 4: Triphenyltin Chloride: Results of Skin Irritation Tests in Rabbits

Time	Rabbit	Sco	ore	Combined Average
		Intact	Abraded	
24 hours	1	3	3	
110ui s	2	4	4	
	3	3	3	
	4	4	4	
	5	3	3	
	6	1	1	
	Average	3.0	3.0	
72 hours	1	2	4 eschar	
110015	2	2	4 11	
	3	2	4 11	
	4	2	4 "	
	5	2	4 11	
	6	1	4 "	
	Average	1.8	4.0	
				2.95

Severely irritating

Table 5: Triphenyltin Acetate: Results of Eye Irritation Tests in Rabbits. Compound Undiluted

Time	Rabbit	S	Score A	lccord:	ing to Pa	rt Affect	ced	Average
		Corne		Iris	C	Conjunctiv	<i>r</i> a	Total Score
		Opacity	Area		Redness	Chemosis	Discharge	
24 hrs.	1	4	4	2	2	4	3	
	2	4	4	2	3	4	3	
	3	4	4	2	3	4	3	
	4	4	4	2	2	4	3	
	5	4	4	2	2	4	3	
								110
48 hrs.	1	4	4	2	2	4	3	
III's.	2	4	4	2	3	4	3	
	3	4	4	2	3	4	3	
	4	4	4	2	2	4	3	
	5	4	4	2	2	4	3	
								110
72	1	4	4	2	2	4	3	
hrs.	2	4	4	2	3	4	3	
	3	4	4	2	3	4	3	
	4	4	4	2	2	4	3	
	5	4	4	2	2	4	3	
								110
One Month		lestructi ermanent	on com	plete				

Table 6: Triphenyltin Chloride: Results of Eye Irritation Tests in Rabbits. Compound Undiluted

Time	Rabbit	S	Score .	Accord	ing to Pa	art Affect	ted	Average Total
		Corne	ea	Iris	(	Conjunctiv	/a	Score
		Opacity	Area		Redness	Chemosis	Discharge	
24 hrs.	1	4	4	2	2	4	3	
m s.	2	4	4	2	2	4	3	
	3	4	4	2	2	4	3	
	4	4	4	2	2	4	3	
	5	4	4	2	3	4	3	
	6	4	4	2	3	4	3	
								110
48	1	4	4	2	2	4	3	
hrs.	2	4	4	2	2	4	3	
	3	4	4	2	2	4	3	
	4	4	4	2	2	4	3	
	5	4	4	2	3	4	3	
	6	4	4	2	3	4	3	
								110
72	1	4	4	2	2	4	3	
hrs.	2	4	4	2	2	4	3	
	3	4	4	2	2	4	3	
	4	4	4	2	2	4	3	
	5	4	4	2	3	4	3	
	6	4	4	2	3	4	3	
								110
One Month	l	destructi permanent		nplete				

Table 7: Triphenyltin Acetate: Results of Eye Irritation Tests in Rabbits. Compound Diluted 1% in Corn Oil

Time	Rabbit	S	Score A	Accord	ing to Pa	irt Affect	ced	Average Total
		Corne	ea.	Iris	0	Conjunctiv	7a	Score
		Opacity	Area				Discharge	
24 hrs.	1	1	1	0	2	2	2	
	2	0	0	0	1	1	0	
	3	0	0	0	1	1	0	
	4	0	0	0	0	0	0	
	5	0	0	0	1	0	1	,
	6	0	0	0	1	1	0	
								5.5
48	1	1	1	0	2	3	2	
hrs.	2	0	0	0	1	1	0	
	3	0	0	0	1	1	0	
	4	0	0	0	<u>+</u>	<u>+</u>	0	
	5	0	0	0	1	0	0	
	6	0	0	0	1	1	0	
								5.8
72 hrs.	1	0	0	0	2	2	1	ļ
111.2.	2	0	0	0	1	1	0	
	3	0	0	0	1	1	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	1	1	0	
								3.7

Moderately irritating

Table 8: Triphenyltin Chloride: Results of Eye Irritation Tests in Rabbits. Compound Diluted 1% in Corn Oil

Time	Rabbit	S	Score	Accord	ing to Pa	art Affect	ced	Average
		Corne		Iris	(	Conjunctiv	7a.	Total Score
		Opacity	Area		Redness	Chemosis	Discharge	
24 hrs.	1	0	0	0	0	0	0	
	2	1	1	0	1	1	1	
	3	0	0	0	1	0	0	
	4	0	0	0	1	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	1	0	0	
								2.8
48 hrs.	1	0	Ö	0	0	0	0	
mrs.	2	0	0	0	2	1	1	
	3	0	0	0	1	0	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
								1.7
72 hrs.	1	0	0	0	0	0	0	
in s.	2	0	0	0	1	1	0	
	3	0	0	0	0	0	0	i
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
								.7

Slightly irritating

Table 9: Dioctyltin Monolaurylmaleate: Results of Eye Irritation Tests in Rabbits. Compound Undiluted

Time	Rabbit		Score	Accord	ing to Pa	art Affec	ted	Average Total
		Corne	ea	Iris	(	Conjuncti	va	Score
		Opacity	Area	<b></b>	Redness	Chemosis	Discharge	
24 hrs.	1	2	4	1	1	3	2	
	2	1	4	0	2	3	2	
	3	2	4	0	2	3	3	
	4	1	3	0	2	3	2	
	5	1	3	0	2	4	2	
	6	1	4	0	2	3	2	
								39.8
48 hrs.	1	2	4	0	2	4	2	
1115.	2	1	4	0	2	3	2	
	3	5	4	0	2	2	1	
	4	1	2	0	1	.5	1	
	5	1	3	0	1	3	1	
i	6	1	4	0	1	2	1	
								<i>3</i> 5.2
72 hrs.	1	2	2	0	2	3	1	
111 5.	2	1	1	0	0	1	1	
	3	2	4	0	1	2	1	
	4	1	1	0	0	1	0	
	5	0	0	0	0	1	1	
	6	1	4	0	1	1	1	
								21.0

Severely irritating

Table 10. Trioctyltin Oxide: Results of Eye Irritation Tests in Rabbits. Compound Undiluted

Time	Rabbit	S	core A	ccordi	ng to Par	rt Affecte	ed	Average Total
		Corn	ea	Iris	(	Conjunctiv	7a.	Score
		Opacity	Area		Redness	Chemosis	Discharge	
24 hrs.	1	0	0	0	0	1	1	
mrs.	2	0	0	0	1	1	0	
	3	0	0	0	2	2	1	
	4	0	0	0	0	1	0	
	5	0	0	0	1	0	0	
								4.4
48 hrs.	1	0	0	0	+	+	1	
1115.	2	0	0	0	1	1	0	
	3	0	0	0	1	2	2	
	4	0	0	0	1	0	0	
	5	0	0	0	0	1	0	
								4.4
72	1	0	0	0	0	0	1	
hrs.	2	0	0	0	0	0	0	
	3	0	0	0	1	1	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
								1.2

Slightly irritating

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CECATSTRIAGE TRACKING DRASE ENTRY FORM  INFORMATION REQUESTED. FLWF DATE: 650, NO INFO REQUESTED. 652 UNFO REQUESTED (TECH) 654 UNFO REQUESTED (VOL. ACTIONS) 654 UNFO REQUESTED (NE. ACTIONS) 654 UNFO REQUESTED (REPORTING PATIONALE) DEFOSITION FAURE REFER TO CHEMICAL SCREENING 678)CAP NOTICE 678)CAP NOTICE 678)CAP NOTICE 678)CAP NOTICE 678)CAP	6334-23-8	### MAN TITE:  ### MAN EXPOS (PROD CONTAM) 81 #2 #4  ### MAN EXPOS (ACCIDENTAL) 81 #2 #4  ### METABRHARMACO (AUMAN) 81 #2 #4  METABRHARMACO (AUMAN) 81 #2 #4  METABRHARMACO (AUMAN) 81 #2 #4	ROT LOW ACUTE Oral Toxicity, eye irritathan RoT MED A CUTE Oral Toxicity, eye irritathan MED A CUTE Oral Toxicity, eye irritathan MED A CUTE Oral Toxicaty, eye irritathan Irritathan Exercise Toxicathan Exercise Irritathan
CECATS DATA:  CHECATS Submission # BEHQ. 1093 - 13419 SEO. #   TYPE. INT. SUPP. PLAN.  SUBMITTER NAME. EF. PROCESSION NO. # L.  SUB. DATE: OSION 192 OF DATE: 10 08 192	Acetic acid, (tripheny(stany))-	NEORMATION TIPE:   P. F.C.   INFORMA	TRACORRAY RON-CRI INVENTORY ONGOING REVIEW S  (TES)  CAS 5R NO.  (CONTINUE)  (CAS 5R NO.  (CONTINUE)

12619A

medium

Triphenyltin chloride: Acute oral toxicity in rats is of 14% concern. Single oral doses to Long-Evans male rats (2/group) at levels of 80, 160, 320, 640, 1,250, 2,500, and 5,000 mg/kg were lethal (0/2, 0/2, 0/2, 2/2, 2/2, 2/2, and 2/2, respectively). Necropsy revealed abdominal hemorrhages at  $\geq 1,250$  mg/kg.

ND

Triphenyltin chloride: Acute inhalation toxicity in rats could not be determined as the concentration was not specified. Single 4-hour inhalation exposures to six rats were not lethal. There were no signs of toxicity.

Η

Triphenyltin chloride: Dermal irritation in rabbits is of high concern. Application of 0.1 g of the substance to the intact and abraded skin of six rabbits resulted in severe irritation and corrosion. Slight to severe erythema and edema were seen at both intact and abraded sites at 24 hours, persisting at 72 hours in all animals. At 72 hours, severe irritation and eschar occurred at abraded sites of all rabbits.

H

Triphenyltin chloride (undiluted): Eye irritation in rabbits is of high concern. Instillation of 0.1 g of the substance undiluted into the conjunctival sac of one eye of six rabbits resulted in complete and permanent destruction of the eye.

L

Triphenyltin chloride (diluted): Eye irritation in rabbits is of low concern. Instillation of 0.1 mL of the substance diluted (1% suspension in corn oil) into the conjunctival sac of one eye of six rabbits resulted in slight irritation. At 24 hours, slight conjunctival irritation was seen in 4/6 rabbits and slight corneal opacity occurred in 1/6. Slight conjunctival irritation persisted in 1/6 rabbits at 72 hours.

М

Triphenyltin acetate: Acute oral toxicity in rats is of moderate concern. Single oral doses to Long-Evans male rats (2/group) at levels of 80, 160, 320, 640, 1,250, 2,500, and 5,000 mg/kg were lethal (0/2, 0/2, 1/2, 1/2, 1/2, 2/2, and 2/2, respectively). Necropsy revealed abdominal hemorrhages at  $\geq$ 1,250 MD

Triphenyltin acetate: Acute inhalation toxicity in rats could not be determined as the concentration was not specified. Single 4-hour inhalation exposures (concentration not specified) to six rats were not lethal. There were no signs of toxicity.

н

Triphenyltin acetate: Dermal irritation in rabbits is of high concern. Application of 0.1 g of the substance to the intact and abraded skin of six rabbits resulted in severe irritation and corrosion. Slight to moderate erythema and edema were seen at both intact and abraded sites at 24 hours, persisting at 72 hours in 5/6 intact and 6/6 abraded. At 72 hours, severe irritation and eschar were noted at abraded sites of 4/6 rabbits.

Triphenyltin acetate (undiluted): Eye irritation in rabbits is of high concern. Instillation of 0.1 g of the substance undiluted into the conjunctival sac of one eye of six rabbits resulted in complete and permanent destruction of the eye.

М

Triphenyltin acetate (diluted): Eye irritation in rabbits is of moderate concern. Instillation of 0.1 mL of the substance diluted (1% suspension in corn oil) into the conjunctival sac of one eye of six rabbits resulted in moderate irritation. At 24 and 48 hours, slight to moderate conjunctival irritation was seen in 5/6 and slight corneal opacity was seen in 1/6. The conjunctival irritation persisted in 4/6 at 72 hours.

A 14

Dioctyltin monoaurylmaleate: Eye irritation in rabbits is of moderate concern. Instillation of 0.1 g of the substance undiluted into the conjunctival sac of one eye of six rabbits resulted in severe irritation. At 24 hours, all rabbits exhibited extensive corneal opacity and slight to severe conjunctival irritation. Mild iritis was also seen in one rabbit. Corneal opacity and conjunctival irritation persisted in 5/6 and 6/6 rabbits, respectively, at 72 hours.

L

Trioctyltin oxide: Eye irritation in rabbits is of low concern. Instillation of 0.1 g of the substance undiluted into the conjunctival sac of one eye of five rabbits resulted in slight irritation. Slight conjunctival irritation was seen in all rabbits at 24 hours, persisting in 2/5 at 72 hours.